

### 3. The Claims Are Not Obvious

Claims 1 - 20 stand rejected for obviousness under 35 U.S.C. § 103(a) based on the art cited above. Applicants respectfully traverse. The Court of Appeals of the Federal Circuit has held that:

"[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. . . . If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent."

*In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Applicants maintain the Examiner has not set out a *prima facie* case of obviousness. Assuming *arguendo* the Examiner has established a *prima facie* case of obviousness, however, Applicants respond and rebut with evidence provided through reference to the Specification in the application as filed.

#### A. A *Prima Facie* Case of Obviousness is Not Established

A *prima facie* case of obviousness requires the Examiner to cite to a combination of references which (a) discloses the elements of the claimed invention, (b) suggests or motivates one of skill in the art to combine those elements to yield the claimed combination, and (c) provides a reasonable expectation of success should the claimed combination be carried out. See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990); *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988). This threshold showing has not been met.

#### i. There is no basis for the combination

The Examiner has combined two references without giving a reason for the combination. This is improper:

"[W]hen the PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears."

*In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). The Examiner points to no teaching in any reference which suggests the combination of this art. Rather, the Examiner presents a conclusory statement - not reasons. A conclusory statement does not satisfy the Examiner's burden to establish a *prima facie* case of obviousness.

**ii. The Examiner is using hindsight**

The Examiner has argument that it would be obvious to modify the teachings of the references to create the claimed invention:

"[i]t would have been obvious to one skilled in the art to include such electronic measuring means as those of Palti in the device of Brauker *et al.*, in order to merely process the information obtained by the sensor, indicative of the amount of glucose concentration present in the sample."

(see Office Action, page 3). But the Examiner can point to nothing in the reference that suggests the modifications. The MPEP § 2143.01 specifically provides that "THE PRIOR ART MUST SUGGEST THE DESIRABILITY OF THE CLAIMED INVENTION" (emphasis in original).<sup>1</sup> Since the references cited against the claims do not suggest the modification, the Examiner's position is improper.

Indeed, it would appear that the Examiner must have used hindsight in order to add the "electronic measuring means" element of Palti to the device of the Brauker reference. The Examiner, now familiar with the invention through the review of the present specification, is looking at the invention in retrospect. This is not permitted:

"To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher."<sup>2</sup>

In the present case, there is no teaching, suggestion, or motivation to make the modification now offered by the Examiner.

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<sup>1</sup> Obviousness can only be established by *modifying* the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

<sup>2</sup> *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983)

**iii. No further response is required**

Because the Examiner has not satisfied the Examiner's burden by establishing a *prima facie* case, the law requires nothing further from the Applicants. That is to say, the Applicants are not required to address the merits of the Examiner's rejections if the combination of references is not justified in the first place. This point is well-illustrated by the recent case of *In re Rouffet*, 149 F.3d. 1350, 47 USPQ 2d 1453. In that case, the Federal Circuit agreed with the Board that the combination of references - if proper - provided all of the elements of the claim sought to be patented. However, the Federal Circuit noted that there was no justification for the combination of the art, and thus the question of whether the combination taught the claimed invention was premature.

**B. The Cited Art Does Not Teach The Claimed Subject Matter**

Without waiving the above argument, but to further the prosecution, the arguments of the Examiner are herein addressed on their merits. Applicants note that Claim 12 recites, "[t]he biological fluid measuring device of Claim 11, wherein said glucose determining means comprises a membrane containing glucose oxidase." The combined teaching of Brauker *et al.* and Palti, however, are *totally silent* on the use of *any* oxidase in a biological fluid measuring device. All of the elements recited in the invention as originally claimed are not taught by the combination of Brauker *et al.* with Palti. Therefore, the cited art is inadequate to sustain a rejection of all the claims in the application as originally filed.

In order to further the business interests of the Applicants and without acquiescing to the arguments of the Examiner, the Applicants have canceled claims 1-10 (without prejudice to prosecuting these same claims in the future) and amended

claim 11 (without prejudice to prosecuting claim 11 as originally filed in the future) to specify that the membrane is impregnated with an oxidase.

**C. The Present Invention Discloses Substantial Improvements Over The Prior Art**

The instant application contains specific data reciting improvements over the prior art. Consistent with the holding *In re Soni* [see 34 USPQ 2d 1684, 1687-88 (Fed. Cir. 1995)], therefore, these substantial improvements (including, but not limited to, prevention of environmental stress cracking) renders inapplicable the Examiner's objection to claims 1-20 based on U.S. patent 5,741,330 to Brauker *et al.* under 35 U.S.C. §103(a).

The Applicants identified environmental stress cracking as a fundamental limitation of the prior art. Specifically, the Applicants state:

"[b]oth hypochlorite and H<sub>2</sub>O<sub>2</sub> are known to break down a variety of polymers, including polyurethane, by a phenomenon referred to as environmental stress cracking. [Phillips *et al.*, J. Biomat. Appl., 3:202-227 (1988); Stokes, J. Biomat. Appl. 3:228-259 (1988)]. Indeed, environmental stress cracking has been shown to limit the lifetime and performance of an enzyme-active polyurethane membrane stretched over the tip of a glucose sensor. [Updike *et al.*, Am. Soc. Artificial Internal Organs, 40:157-163 (1994)]."

Application as filed, pages 19-20. The Applicants addressed this shortcoming in the prior art by teaching:

"a bioprotective membrane 33 (that) covers the enzyme membrane 32 and serves, in part, to protect the sensor from external forces that may result in environmental stress cracking of the enzyme membrane 32."

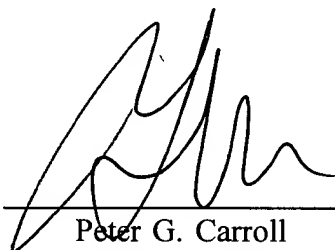
Application as filed, page 16, lines 2-5.

Viewed in light of the teachings of the present specification, the Examiner's rejection of the invention as obvious is improper. The specifically claimed elements and their relationship to one another achieve benefits not expected or taught by the cited art.

**CONCLUSION**

Applicants believe that the arguments set forth above traverse the Examiner's rejections and therefore request that these grounds for rejection be withdrawn for the reasons set forth above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at 617-252-3353.

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